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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,102	03/30/2004	Andrew A. Conway	208.1005.01	6571

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EXAMINER	
MILLER, MARINA I	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/815,102	CONWAY, ANDREW A.	
	Examiner	Art Unit	
	Marina Miller	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' submission filed on 12/19/2005 is acknowledged. Claims 1-23 are pending. Claims 1-23 presently are under examination.

Applicants' arguments have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are applied.

Claim Rejections - 35 USC § 101

Non-Statutory Subject Matter

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant claims were previously rejected as being directed to non-statutory subject matter. Applicants argue that claims 1 and 11 do recite an actual transformation of data because the method "transforms" genotype data into a region in genome that includes markers exhibiting particular pair of alleles. Applicants also argue that this transformation does have a practical application. Specifically, applicants state that the method results in cost savings and cost savings are eminently practical. Applicants' arguments have been considered, but are found not persuasive.

In response to the argument, it is noted that in determining whether the claim recites a "practical application," the focus is on whether the final result achieved by the claimed method is useful, tangible, and concrete. Applicants are directed to Interim Guidelines for Examination of

Patent Applications for Patent Subject Matter Eligibility (10/27/2005), specifically pages 19-22 for clarification of the requirement "useful, tangible, and concrete result."

In the instant case, the "result" of the method is determining a region of markers with highest scores. As it is stated in the previous office action, the instant claims do not recite tangible expression of the determination of the region of markers and/or locating a statistically significant gap in the scores (*see* instant claim 10), nor any recitation of an actual (*i.e.*, concrete) result in a form useful to one skilled in the art. The fact that conducting the instant method is cost efficient does not make the actual result of the method (*i.e.*, a determined region of markers) useful, tangible, and concrete in order to satisfy the requirement under 35 U.S.C. 101. Thus, the method does not recite steps of producing something that is concrete, useful, and tangible, and is not statutory.

Lack of Utility

Claims 1-23 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The instant claims were previously rejected for lack of patentable utility. Applicants argue that utility of the "invention is not 'for determining recessive disease in inbred population,' but rather to determine a region of a genome for more cost-effective sequencing." (p. 10-11 of the response). The examiner reviewed the specification, but did not find such a utility (*i.e.*, "more cost effective sequencing") disclosed. Thus, the alleged utility is not discloses and is not apparent. Moreover, the alleged utility is not commensurate with the claimed invention because there is no step or other limitation in the instant claims indicative or otherwise related to "determining a region for more cost-effective sequencing." The specification does disclose that

the invention is useful for generating a general region of a human genome responsible for genetically-linked recessive diseases and detecting recessive diseases in inbred population (p. 1-2). However, the disclosed utility is also not applicable to the instant claims for the reasons stated in the previous office action.

Applicants further argue that the invention does not require further research to identify a real world utility. Applicants also argue that the instant invention has substantial (pointing out where in the genome to look for a region) and specific utility (identifying a region of a genome for cost-effective sequencing) (p. 12-14 of the response).

In response to the arguments, it is noted that the instant method is not equivalent to a method described in the MPEP and cited by applicants on p. 12 as having a "real world" use because the instant method does not have a stated correlation between a recessive disease and a determined score and is not particular to a specific disease or trait being claimed and is applicable to the general class of traits. Specifically, there is no evidence disclosing any connection of the scores to affected people, *i.e.*, whether the scores actually reflect presence of a recessive disease in a region and whether the region is actually associated with a disease. Therefore, determining a region responsible for a recessive trait would require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use, as it stated in the previous office action. Further, the instant invention does not have specific utility because absent disclosure about, for example, allele frequencies in affected and unaffected population, and/or correlation between a region of markers and a disease to be diagnosed, the asserted utility is not specific. Also, the alleged specific utility (*i.e.*, determining a region for

more cost-effective sequencing) is not applicable to the instant claims (*see above* for the reasoning).

For the reasons stated above an in the previous office action, the rejection of claims 1-23 under 35 U.S.C. 101 is maintained for lacks patentable utility.

Claim Rejections - 35 USC § 112

Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 7-9, 11, 17-19, and 21, as amended, recite the limitation a "highest or next-highest" merged score. The metes and bounds of the determining "highest or next-highest" merged score is not clear because a range of scores and/or the criteria of determining "highest" score is not clear, and neither claims nor the specification defines the limitation. As the intended limitation is not clear, claims 1-23 are indefinite.

Claim Rejections - 35 USC § 102

Claims 1-6, 9-16, and 19-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Arbour et al., *Human Mol. Genet.*, 6(5):689-694 (1997).

The claims were previously rejected over Arbour. Applicants argue that Arbour does not disclose merging scores under different assumptions, and specifically when markers are autozygous. Applicants' arguments have been considered, but are found not persuasive.

In the response to the arguments, it is noted that Arbour discloses "the assumption that there is a high probability that individuals from an inbred population affected with an autosomal

recessive disease inherited both copies of the disease gene from a single common ancestor" (*i.e.*, the assumption of autozygousity) (p. 689, right col.). Arbour further teaches merging scores comprising two types of scores because he teaches comparing homozygous markers to those of the unaffected individuals (p. 689, right col.), calculating LOD score which comprises the likelihood of observing the actual measured value for a marker (*e.g.*, autozygous) and the likelihood of observing the actual measured value for not autozygous marker (*i.e.*, not from founder) (*e.g., see* LOD score table 1 and p. 690, right col.), and merging a set of scores for each marker (*see* tables 1-2 in conjunction with fig. 3). Arbour's LOD score is similar to a score disclosed in the instant specification on p. 18-20. Arbour also discloses determining a region of markers with a high score (p. 690, right col.) (*e.g.*, maximum LOD score). Thus, the examiner maintains that Arbour discloses merging scores under different assumptions, and specifically when markers are autozygous. For the reasons stated above and in the previous office action, the rejection of claims 1-6, 9-16, and 19-21 is maintained. Arbour also discloses genotyping regions around markers (*i.e.*, determining sequence). Thus, Arbour anticipates claim 22-23.

Claims 1-4, 11-14, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kruglyak et al., *Am. J. Hum. Genet.*, 56:519-527 (1995).

The claims were previously rejected over Kruglyak. Applicants argue that Kruglyak does not disclose merging scores under different assumptions, and specifically when markers are autozygous. Applicants' arguments have been considered, but are found not persuasive.

In the response to the arguments, it is noted that Kruglyak discloses calculating the multipoint LOD score wherein individuals are homozygous by descent (inherited a single

disease-causing allele from a common ancestor, *i.e.*, autozygous; p. 519 and 520, right col.). LOD score comprises a score from effected and non-effected individuals (similar to a score disclosed in the instant specification on p. 18-20). Kruglyak further discloses "combined scores" (p. 522 and fig. 3). Thus, the examiner maintains that Kruglyak discloses merging wherein a score includes those for autozygous and not autozygous markers.

Claim Rejections - 35 USC § 103

Claims 7-8 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arbour et al., *Human Mol. Genet.*, 6(5):689-694 (1997), as applied to claim 1-6, 9-16, and 19-23, in view of Kruglyak et al., *Am. J. Hum. Genet.*, 56:519-527 (1995).

The claims were previously rejected over Arbour and Kruglyak. Applicants did not specifically address the combination of references. The examiner maintains that Arbour anticipates the method of claims 1-6, 9-16, and 19-23, as set forth above. Thus, the rejection of claims 7-8 and 17-18 over the combination of references is also maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-5, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph. D. can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Miller
Examiner
1631

MM

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
3/1/06